



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2019 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2019.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at

<https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>

or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888,

Lisa.Kable@fda.hhs.gov. For general questions, you may also email the Center for Veterinary Medicine (CVM) at cvmagdufa@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 741 of the FD&C Act (21 U.S.C. 379j-21) establishes three different types of user fees: (1) fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j-21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j-21(b)). Base revenue amounts established for fiscal years after FY 2019 are subject to adjustment for inflation and workload. Workload increases will be adjusted for excess collections after FY 2020 (21 U.S.C. 379j-21(c)). The target revenue amounts for each fee category for FY 2019, are as follows: for application fees, the target revenue amount is \$4,584,000; for product fees, the target revenue amount is \$6,876,000; and for sponsor fees, the target revenue amount is \$6,876,000.

For FY 2019, the generic new animal drug user fee rates are: \$424,444 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$212,222 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); \$15,486 for each generic new animal drug product; \$150,098 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$112,574 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$75,049 for each generic new animal drug sponsor

paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2019 product and sponsor fees by December 31, 2018. These fees will be due by January 31, 2019. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2018, and will remain in effect through September 30, 2019. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2019

A. Statutory Fee Revenue Amounts

AGDUFA III, Title II of Pub. L. 115-234, specifies that the aggregate revenue amount for FY 2019 for all generic new animal drug user fee categories is \$18,336,000 (rounded to the nearest thousand dollars) (21 U.S.C. 379j-21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments--one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see 21 U.S.C. 379j-21(c)(2)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years. The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than

PC&B costs to total FDA costs. Because the adjustment for inflation does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for inflation.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j-21(c)(3)).

AGDUFA III specifies that FDA shall calculate the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions). Because the adjustment for workload does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for workload changes.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 741(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections, for the second preceding fiscal year, up to the amount of the fee revenue increase. Since this provision will not take effect until FY 2021, FDA will not reduce the FY 2019 fee revenue amount for excess collections.

E. FY 2019 Fee Revenue Amounts

AGDUFA III specifies that the revenue amount of \$18,336,000 (rounded to the nearest thousand dollars) for FY 2019 is to be divided as follows: 25 percent, or a total of \$4,584,000, is to come from application fees; 37.5 percent, or a total of \$6,876,000, is to come from product fees; and 37.5 percent, or a total of \$6,876,000, is to come from sponsor fees (21 U.S.C. 379j-21(b)).

*III. Abbreviated Application Fee Calculations for FY 2019**A. Application Fee Revenues and Numbers of Fee-Paying Applications*

Each person that submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j-21(a)(1)). The term “abbreviated application for a generic new animal drug” means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) (21 U.S.C. 379j-21(k)(1)). The application fees are to be set so that they will generate \$4,584,000 in fee revenue for FY 2019.

To set fees for abbreviated applications for generic new animal drugs to realize \$4,584,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2019.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates annually. FDA is making estimates and applying different assumptions for two types of full fee submissions: original submissions of abbreviated applications for generic new animal drugs and “reactivated” submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed

fees (21 U.S.C. 379j-21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (i.e., FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as “reactivated” applications.

Also, under AGDUFA III, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j-21(a)(1)(C)(ii)).

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications for which fees will be paid in FY 2019 will equal the average number of submissions over the five most recently completed years of the AGDUFA program (FY 2013-FY 2017).

The average number of original submissions of abbreviated applications for generic new animal drugs over the five most recently completed years is 9.2 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 3.2 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 10.8 anticipated full fees.

In prior years, FDA had estimated the number of reactivations of abbreviated applications for generic new animal drugs that had been originally submitted prior to July 1, 2008. Over the years, that number has decreased to the point that FDA no longer expects to receive any reactivations of applications initially submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.8 fee-paying generic new animal drug applications in FY 2019 (9.2 original applications paying a full fee and 3.2 applications paying a half fee).

B. Application Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 10.8 abbreviated applications that pay the fee will generate a total of \$4,584,000. To generate this amount, the fee for a generic new animal drug application will have to be \$424,444 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or \$212,222.

IV. Generic New Animal Drug Product Fee Calculations for FY 2019

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j-21(a)(2)). The term “generic new animal drug product” means each specific strength or potency

of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j-21(k)(6)). The product fees are to be set so that they will generate \$6,876,000 in fee revenue for FY 2019.

To set generic new animal drug product fees to realize \$6,876,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2019. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of June 2018, FDA estimates a total of 448 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 448 products will be subject to this fee in FY 2019.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2019, FDA is estimating that one percent of the products invoiced, or four products, will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j-21(d)). FDA has made this estimate at one percent this year, based on historical data over the past five completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 444 (448 minus 4) products will be subject to product fees in FY 2019.

B. Product Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 444 products that pay fees will generate a total of \$6,876,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be \$15,486.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2019

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j-21(k)(7) and 379j-21(a)(3), respectively). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j-21(a)(3)(C)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j-21(a)(3)(C)). The sponsor fees are to be set so that they will generate \$6,876,000 in fee revenue for FY 2019.

To set generic new animal drug sponsor fees to realize \$6,876,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2019. Based on

the number of firms that meet this definition and the average number of firms paying fees at each level over the five most recently completed years of the AGDUFA program (FY 2013 through FY 2017), FDA estimates that in FY 2019, 14 sponsors will pay 100 percent fees, 19 sponsors will pay 75 percent fees, and 37 sponsors will pay 50 percent fees. That totals the equivalent of 46.75 full sponsor fees (14×100 percent or 14, plus 19×75 percent or 14.25, plus 37×50 percent or 18.5).

FDA estimates that about two percent of all of these sponsors, or 0.94, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j-21(d)). FDA has made the estimate of the percentage of sponsors that will not pay fees at two percent this year, based on historical data over the past five completed years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 45.81 full sponsor fees (46.75 minus 0.94) are likely to be paid in FY 2019.

B. Sponsor Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated equivalent of 45.81 full sponsor fees will generate a total of \$6,876,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be \$150,098. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be \$112,574, and the fee for those paying 50 percent of the full sponsor fee will be \$75,049.

VI. Fee Schedule for FY 2019

The fee rates for FY 2019 are summarized in table 1.

Table 1.--FY 2019 Fee Rates

Generic New Animal Drug User Fee Category	Fee Rate for FY 2019
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	\$424,444
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	\$212,222
Generic New Animal Drug Product Fee	\$15,486

100 Percent Generic New Animal Drug Sponsor Fee ¹	\$150,098
75 Percent Generic New Animal Drug Sponsor Fee ¹	\$112,574
50 Percent Generic New Animal Drug Sponsor Fee ¹	\$75,049

¹An animal drug sponsor is subject to only one fee each fiscal year.

VII. Fee Waiver or Reduction; Exemption from Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2019. However, a new exemption from fees was established by AGDUFA III, as follows:

Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under AGDUFA based only on the submission of the supplemental abbreviated application (21 U.S.C. 379j-21(d)(2)).

VIII. Procedures for Paying FY 2019 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2019 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2018. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> or the Pay.gov payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select “Pay Now”

to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number, beginning with the letters "AG", on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314-418-4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

The tax identification number of FDA is 53-0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One--Create a user account and password. Log onto the AGDUFA website at <https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm> and scroll down the page until you find the link "Create AGDUFA User Fee Cover Sheet." Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two--Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it

electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three--Send the payment for your application as described in section VIII.A.

Step Four--Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2018, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2019 using this fee schedule. Fees will be due by January 31, 2019.

FDA will issue invoices in November 2019 for any products and sponsors subject to fees for FY 2019 that qualify for fees after the December 2018 billing.

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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